IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

AMNIOTIC THERAPIES LLC, 11496 Luna Road Suite 800 Farmers Branch, TX 75234-9417	)	
Plaintiff,	)	Case No. 3:16-cv-2412
v.	)	
UNITED STATES FOOD AND DRUG ADMINISTRATION, 200 Independence Avenue, S.W. Washington, D.C. 20201	)	
Defendant.	)	

COMPLAINT

Plaintiff Amniotic Therapies, LLC ("Amniotic Therapies") for its Complaint in this matter avers and alleges as follows:

Nature of Action

1. Two days ago (on August 16, 2016), the United States Food and Drug Administration ("FDA") applied a serious enforcement sanction against Amniotic Therapies: an order (hereafter, the "FDA Order") that requires Amniotic Therapies to immediately halt manufacturing and distribution of designated products and, within five working days, to recall all batches of those products, and to destroy all those products. The FDA Order is unfounded. FDA is permitted to issue such an order only on the basis of a serious threat of infection caused by products. But, in fact, the cases on which FDA relied in issuing the Order occurred only after administration of products different from the ones addressed by the FDA Order, and those

infections were likely caused by an error by surgical personnel, not by contamination of the product. Moreover, the FDA's request for an immediate shutdown is outrageous, in the light of the fact that FDA concluded its inspection of Amniotic Therapies facilities three and one half months ago, and all the findings on which FDA bases its Order were known at that time. The Order and FDA regulations do not permit Amniotic Therapies to stay the effectiveness of the Order through a request for an administrative hearing (only an order of destruction can be held in abeyance with an administrative hearing), and emergency intervention by this Court is the only avenue for Amniotic Therapies to avoid the serious consequences that will undoubtedly otherwise result from the Order. Amniotic Therapies would likely be required to lay off three of its five employees, and could not survive until permission would ultimately be given by FDA to reopen its manufacturing lines. Because the FDA Order is arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law, Amniotic Therapies seeks emergency relief staying the effectiveness of the Order until this Court can more carefully review the record, at which point Amniotic Therapies will ask the Court to order FDA to withdraw the Order.

Parties

2. Plaintiff Amniotic Therapies is a corporation duly organized and existing under the laws of the State of Nevada, with its principal place of business at 11496 Luna Road, Suite 800, Farmers Branch, TX 75234-9417781. Amniotic Therapies is engaged in the research, development, processing and distribution of biological human tissue products derived from human amnion.

3. Defendant FDA is an agency within the U.S. Department of Health and Human Services ("HHS"). HHS maintains offices at 200 Independence Avenue, S.W., Washington, D.C. 20201.

Jurisdiction and Venue

4. This action arises under the Public Health Service Act, codified at 42 U.S.C. § 264, and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551-559, 701-706; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202; 28 U.S.C. § 1361. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1361.

5. This Court has personal jurisdiction over FDA because it conducts business in this District, and because FDA's unlawful conduct complained of herein was committed against, and has irreparably harmed, a party located in this District.

6. FDA's unlawful decision to issue the August 16, 2016, Order is a final agency action, subject to challenge as being arbitrary and capricious, an abuse of discretion, or otherwise not in accordance to law, which is reviewable under 5 U.S.C. § 706(1).

7. There exists an actual and justiciable controversy between Amniotic Therapies and FDA requiring resolution by this Court. Plaintiffs have no adequate remedy at law.

8. Venue is proper in this District under 28 U.S.C. § 1391(e).

Background

9. The FDA Order at issue here, attached to the Motion for Temporary Restraining Order being filed contemporaneously with this Complaint, was delivered to Amniotic Therapies at 3:10 p.m. on Tuesday, August 16, 2016. The FDA Order states that, after an FDA inspection that concluded on May 6, 2016, FDA found conditions that were in violation of FDA regulations, and that the "conditions of manufacture . . . do not provide adequate protections against the risks of communicable disease transmission" because of those regulatory violations, and that there are "reasonable grounds to believe" that the relevant products "pose a danger to health."

10. The Order stated that it did not apply to three products manufactured by Amniotic Therapies: AlphaGEMS, AlphaGEMS Nano, and AlphaGEMS Micro. As to products other than those in the AlphaGEMS family, the Order requires Amniotic Therapies to immediately cease manufacturing and distributing the products, and within five working days, to issue a recall for them, and to destroy them.

11. Amniotic Therapies is registered (under 21 CFR 1271.21 and following) with FDA to process, package, store, label, and distribute amniotic tissue-based wound products. One of its products, AlphaGEMS, is described in its package insert as a "wound covering derived from human amnion," tissue recovered from human placenta. The package insert also stresses that the vial containing AlphaGEMS should not be introduced into the sterile field by surgeons, instructing personnel to "open the foil pouch" containing the product "outside the sterile field," and adding that the physician should withdraw the "allograft" (the technical name for the contents of the vial to be administered to a patient) into a "sterile syringe".

12. Amniotic Therapies also processes and distributes amniotic tissue-based wound products for other purposes. The AlphaGEMS product discussed above is a liquid, contained in a vial. The AlphaPATCH product is a solid product that is packaged in a pouch, with similar instructions as to introduction into the sterile field (only the inner pouch, which has been terminally sterilized, may be introduced into the sterile field).

13. Amniotic Therapies has received only four complaints about use of its products in patients since distribution began in September 2014. All four were reports from St. Vincent's Hospital in Cleveland, Ohio. The surgeon who used the products on these four patients did not sterilize the vials before bringing them into the sterile field, or withdraw the contents into a sterile syringe and bring only the pre-loaded sterile syringe into the sterile field.

14. FDA conducted an inspection at Amniotic Therapies in 2015, and a second inspection that ended on May 4, 2016. At the end of the 2016 inspection, FDA issued a report of inspectional observations. Amniotic Therapies responded to the 483 promising corrective actions to address the observations.

15. The FDA 483 (Report of Inspection) reported that its findings were based, in part, on MedWatch reports that had been filed with FDA about the four patients discussed above, and on tests that were conducted on AlphaGEMS vials, reportedly unused, that were in the possession of St. Vincent's Hospital.

16. During and subsequent to the inspection, Amniotic Therapies repeatedly asked the FDA inspectors for copies of the MedWatch reports, and for copies of shipping documentation relating to the vials from St. Vincent's, which were reportedly tested at the University of Alabama in Birmingham ("UAB"). Amniotic Therapies also requested copies of the testing methodology and any documentation describing the testing facilities. FDA inspectors refused to provide this documentation.

17. The FDA documents relating to the MedWatch reports were received by Amniotic Therapies in virtually illegible form and were only provided on the same day that the FDA Order was delivered to the firm. The requests for information about the UAB tests have not been addressed.

18. Along with the FDA Order, Amniotic Therapies received a Warning Letter, relating only to the AlphaGEMS family of products. The Warning Letter is an indication that FDA believes that the conditions found at a facility are violative, but is not, in itself, an enforcement action against the company. Amniotic Therapies has 15 working days to respond to the Warning Letter.

STATUTORY AND REGULATORY BACKGROUND

19. The production and distribution of amniotic tissue-based wound products, such as those produced by Amniotic Therapies, are regulated under the Public Health Service Act, codified at 42 U.S.C. § 264 which authorizes the Surgeon General of the United States to enforce regulations that permit the destruction of "articles" which are "found to be so infected or contaminated as to be sources of dangerous infection to human beings." The Surgeon General has delegated his authority to promulgate such regulations to FDA.

20. Regulations issued by FDA pursuant to this statutory provision are included in 21 C.F.R. Part 1271. In relevant part, regulations at 21 C.F.R. §1271.440(a)(1) provide that FDA may serve upon the person "a written order" that a human tissue product "be recalled and/or destroyed" upon a finding that an establishment is in violation of the regulations in this part," regulations that require manufacturers of such tissue products to follow current good tissue practices, among other requirements.

21. The APA (5 U.S.C. § 706(2)(A)) directs a reviewing court to "hold unlawful and set aside agency action, findings and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."

22. The FDA Order is not justified. FDA does not have a basis for concluding that the products addressed in the Order present any threat of infection to humans, since any infection was likely caused by improper surgical technique by individuals other than Amniotic Therapies, and beyond Amniotic Therapies' control. Moreover, it is a fundamental deprivation of due process for FDA to refuse to deliver, especially upon Amniotic Therapies' request, documentation that shows critical information about tests conducted on Amniotic Therapies'

products, tests that FDA says establishes contamination on products other than those addressed by the Order.

COUNT I
Declaratory Judgment
(APA – Agency Action in Excess of Statutory Authority)

23. The allegations in paragraphs 1-22 are incorporated herein by reference.

24. The FDA Order, which would impose crippling sanctions on Amniotic Therapies, is explicitly based on FDA's finding that Amniotic Therapies failed to comply with regulations, whereas such an order is statutorily permitted only when products are "so infected or contaminated as to be sources of dangerous infection to human beings." The FDA Order therefore is an impermissible construction of the statutory provision granting the Surgeon General, who has delegated that authority to FDA, authority to issue orders requiring destruction of products and halt of manufacturing and distribution. Thus, FDA's Order is in excess of its statutory authority under the FDC Act and in violation of 5 U.S.C. § 706(2)(C).

25. As a result of the FDA Order, there is a real, substantial and justiciable controversy between Amniotic Therapies and FDA for which there is no adequate legal remedy, and the declaratory relief sought by Plaintiffs will terminate the controversy.

26. WHEREFORE, Plaintiff respectfully requests a declaration that the FDA order dated August 16, 2016, is in excess of its statutory authority under the FDC Act and is in violation of 5 U.S.C. § 706(2)(C).

COUNT II
Declaratory Judgment
(APA – Agency Action Arbitrary, Capricious and Contrary to Law)

27. The allegations in paragraphs 1-26 are incorporated herein by reference.

28. Because the FDA Order is unfounded, coming to unjustified conclusions about an infection threat from the products addressed by the Order, it is arbitrary, capricious and otherwise not in accordance with law in violation of 5 U.S.C. § 706(2)(A).

29. As a result, there is a real, substantial and justiciable controversy between the Amniotic Therapies and FDA for which there is no adequate legal remedy, and the declaratory relief sought by the Plaintiff will terminate the controversy.

30. WHEREFORE, Plaintiff respectfully requests a declaration that the FDA Order dated August 16, 2016, is arbitrary, capricious and in violation of 5 U.S.C. § 706(2)(A).

COUNT III
Injunctive Relief

31. The allegations in paragraphs 1-30 are incorporated herein by reference.

32. As a result of FDA's arbitrary, capricious and unlawful decision to issue the Order dated August 16, 2016, Amniotic Therapies has suffered and will continue to suffer irreparable harm.

33. Amniotic Therapies is likely to succeed on the merits.

34. The balance of equities tips in Amniotic Therapies' favor with respect to the injunctive relief it seeks.

35. The injunctive relief Plaintiff seeks is in the public interest.

36. WHEREFORE, Plaintiff respectfully requests injunctive relief compelling FDA to suspend the effectiveness of the Order dated August 16, 2016, until such time as this Court enters relief under Fed. R. Civ. P. 65(a).

PRAYER FOR RELIEF

37. WHEREFORE, Plaintiff Amniotic Therapies prays that this Court grant the following relief:

(a) Enter an Order declaring that FDA's Order dated August 16, 2016, is in excess of FDA's statutory authority under the Public Health Service Act and is in violation of 5 U.S.C. § 706(2)(C);

(b) Enter an Order declaring that FDA's Order dated August 16, 2016, is arbitrary, capricious and in violation of 5 U.S.C. § 706(2)(A);

(c) Enter an Order compelling FDA to suspend the effectiveness of the Order dated August 16, 2016, temporarily pursuant to Rule 65(b) of the Federal Rules of Civil Procedure pending a preliminary injunction hearing on this matter;

(d) Enter an Order compelling FDA to withdraw the Order dated August 16, 2016, temporarily pursuant to Rule 65(b) of the Federal Rules of Civil Procedure.

Dated: May 19, 2016

Respectfully submitted,

/s/ Joe Kendall
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CERTIFICATE OF SERVICE

I certify that a copy of this document was forwarded via email to Shoshana Hutchinson and Perham Gorji of the Office of Chief Counsel of the U.S. Food and Drug Administration on August 19, 2016.

/s/ Joe Kendall
Joe Kendall